CONSIDERED: /CM/

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPLICANT:	Christopher T. Boyle	CUSTOMER NO.	29,335
SERIAL NO.:	09/716,146	Examiner:	C. Miller
Filed:	11/17/2000	Art Unit:	3738

Title: DEVICE FOR IN VIVO DELIVERY OF BIOACTIVE AGENTS AND METHOD OF MANUFACTURE THEREOF

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REPLY BRIEF TO EXAMINER'S ANSWER

Dear Sir or Madam:

Appellant submits herewith a Reply Brief to the Examiner's Answer mailed on February 23, 2010. The Appellant does not believe any additional fees are due in the Reply Brief; however, the Commissioner is authorized to charge any additional fees regarding this filing, and/or credit any overpayment to deposit account No. 18-2000, of which the undersigned is an authorized user. A duplicated copy of this request is enclosed.

APPELLANT'S REPLY BRIEF

1. Real Party Interest

The real party interest for this patent application is Advanced Bio Prosthetic Surfaces, Ltd., the assignee of the application.

2. Related Appeals and Interference

Board Decision in present application 09/716,146 decided on April 30, 2008, Appeal No. 2007-3212.

Board Decision for related U.S. Application 09/707,685 decided on September 29, 2008, Appeal 2008-1316 (hereinafter the '685 Board Decision").

Board Decision for related U.S. Application 09/783,633 decided on February 21, 2008, Appeal No. 2008-0216.

Board Decision for related U.S. Application 10/672,695 decided on March 31, 2009, Appeal No. 2008-5417.

Board Decision for related U.S. Application 10/258,087 decided on December 20, 2008, Appeal No. 2008-1062

3. Status of Claims

Claims 1-15, 17-19, 21-25, and 29 are canceled. Claims 16, 20, 26-28 are finally rejected under 35 U.S.C. §103(a) as being unpatentable over Brown et al., U.S. Patent No. 6,071,305 in view of Whicher et al., U.S. Patent No. 6,938,668. The rejection of each claim is under appeal.

4. Statement of Amendments

No amendments have been filed after the issuance of the final rejection.

5. Summary of the Claimed Subject Matter

Claim 16 is the sole independent claim pending in the application. Antecedent support for each element in Claim 16 is noted in the parentheses following each claim element:

An endoluminal stent for delivering a bioactive agent to a situs in a body, comprising:

a plurality of vacuum deposited structural elements (Page 5, lines 1-2; Page 10, lines 19-20; Page 11, lines 2-12) forming a radially expandable cylindrical member (Page 6, lines 26-30; Page 7, lines 4-6), the plurality of structural vacuum deposited elements including a complex

finished geometry (See, e.g., Figures 2, 5, 8; Page 8, lines 29-31), each of the plurality of vacuum deposited structural elements having a wall thickness (See, e.g., Figures 3-4; Figures 6-10; Page 10, lines 11 and 23); wherein the vacuum deposited structural elements are fabricated of a metal (Page 8, lines 23-26) and comprise a base layer (Page 11, lines 8-11) and a second layer covering the base layer (Page 11, lines 11-12), further comprising a void space intermediate the base and second layers that is enclosed therebetween (Page 11, lines 12-13);

a plurality of pores passing through the second layer and communicating with the void space such that the void space is open only through the plurality of pores (Page 7, line 3 – Page 8, line 16; Page 10, lines 8-15; Page 11, lines 12-13); and

at least one bioactive agent retained within the void space and elutable through the plurality of pores (Page 8, lines 4-16).

6. Grounds of Rejection to be Reviewed on Appeal

1. *Claims 16, 20, 26-28, and 30-37 are rejected under 35 U.S.C. §103(a) as being unpatentable over by Brown, et al., U.S. Patent No. 6,071,305 in view of Whicher et al., U.S. Patent No. 6,938,668.*

Regarding Applicant's Claim 16, the Examiner has taken the position that Brown discloses an endoluminal stent for delivering a bioactive agent (col. 1, lines 12-20) comprising a plurality of structural elements (12; although only one structural element is shown in Figs. 1 and 2, the Examiner argues that a plurality of structural elements 12 are disclosed as additional possible embodiments at col. 7, lines 34-39; mesh stent, each filament of the plurality of filaments in the mesh being a structural element 12), the structural elements (12) forming a complex geometry (other configurations such as coiling stents, expandable tube stents, roving wire stents, and wire mesh stents, col. 7, lines 34-40), each structural element (12) having a wall thickness (cross sectional thickness of an element 12 as seen in Figs. 3-10) and fabricated from metal (col. 7, lines 11-18) comprising a base layer (considered surface or layer 18) and a second layer (considered abluminal surface or layer 19) covering the base layer (see Figs. 2A, 3, 6, 8 and the Examiner's Attachments 2-5 which more clearly show the location of the "layers"), a void space (20) intermediate the layers and enclosed therebetween, a plurality of pores (22, 28, 54) passing through the second layer (19), such that the void space is only open through the pores (see, e.g., Figs. 3 and 6), and at least one bioactive agent (23; col. 5, lines 1-27).

Regarding the term "layer," the Examiner argues that layer may be considered a portion/thickness/layer of the stent strut (12). The Examiner argues that Applicant's only recitation of the word layer is referral to a deposition process, in which layer upon layer is deposited until forming one unitary device (as shown in Applicant's Figures). The Examiner argues that Applicant's claims refer to a stent which is shown in Applicant's Figs. 2-7, which contains structural elements 21 or 31 shown generally cylindrical, having a longitudinal axis (as shown in Fig. 7) and a round cross-section (as shown in Fig. 3 and 6; Fig. 6 shows two adjacent structural elements). The Examiner argues that the "layers" are not clearly pointed out in the Figures as the specification only refers to "layers" as depositing layer upon layer to form the device shown in the Figures. The Examiners states that it is unclear where one layer starts and ends, but it would appear Applicant is referring to an abluminal and luminal "layer" (referenced as elements 26, 28, 33, and 35).

In support of the argument that Brown's structural elements 12 comprise "layers," the Examiner argues that Brown has shown the same type of structural elements 12, each having a generally round cross-section (Figs. 3-10; which also may be alternately cross-sections, such as a square, col. 6, lines 1-5 which would form flat planar layers) with an inner void space 20. The Examiner argues that, structurally, the elements of Brown are the same as the Applicant's (compare Fig. 2A of Brown to Fig. 7 of Applicant; compares Fig. 3, 6, and 8 of Brown to Fig. 6 of Applicant, keeping in mind that Applicant's Fig. 6 shows two side by side structural elements; see Examiner's Attachments 1-5). The Examiner argues that the structural elements of Brown and Applicant are the same. Therefore, the Examiner argues that a "layer" of Applicant's structural element also may be considered a "layer" of Brown's structural element (see Examiner's Attachments, wherein the second layer is shown shaded to distinguish it from the base layer, both layers being part of structural element 12 which is fully made of metal, both layer are metal).

The Examiner states that although Brown discloses Applicant's claimed endoluminal stent, Brown does not disclose vacuum deposition metal to form the structural elements (i.e. a method of manufacture). The Examiner states that Brown is silent to mention any method of manufacture for stent 11 (the only methods disclosed are for the embodiment in Fig. 17, which is a different embodiment, and a method shown in Figs. 13-18 and col. 11, lines 62-67, which is disclosed as cutting by laser or other conventional cutting means). The Examiner argues that

Whicher teaches in the same field of endoluminal stents, a method of making a stent by using vacuum deposition techniques (col. 3, line 52 – col. 4, line 30) as an improvement over older techniques such as cutting and etching etc. (col. 1, lines 31-51; cutting being the only type mentioned by Brown), in order to improve the properties of the material (discloses control of microstructure, col. 2, lines 6-9; col. 3, lines 18-25; also Whicher discloses the same method of manufacture, vacuum deposition, Whicher process will inherently produce microstructure and heterogeneities, since such control over properties are characteristic of such a process). The Examiner argues that it would have been obvious to one having ordinary skill in the art at the time invention was made to combine Brown's endoluminal stent shape, with Whicher's method of manufacture (vacuum deposition) in order to provide a stent with improved material properties).

The Examiner disagrees with Applicant's argument that Whicher does not teach a plurality of vacuum deposited structural elements including a complex finished geometry. The Examiner argues that both Brown and Whicher disclose stents of complex geometry (see Brown col. 7, lines 34-39, each "structural element" being a strut (12) and the complex geometry being the "expandable tube stents, roving wire stents, and wire mesh stents"). The Examiner argues that Whicher also discloses complex geometries that are vacuum deposited (tailor geometries, col. 3, lines 15-25; col. 6, lines 21-57; Figs. 2 and 3).

Regarding Applicant's Claim 20, the Examiner argues that Brown discloses a degradable plug (biodegradable matrix 27 which is shown in the cavities and extending into the pores as seen in Figs. 3 and 9 for example; col. 8 line 62 – col. 9 line 5).

Regarding Applicant's Claim 26, the Examiner argues that Brown discloses a stent having structural elements comprising a material selected from the group claimed (col. 7, lines 12-18).

Regarding Applicant's Claim 27, the Examiner states that Brown discloses a bioactive agent selected from the group claimed (col. 5, lines 1-27).

Regarding Applicant's Claim 28, the Examiner states that Brown discloses a void space comprising a plurality of independent internal cavities along the length of the structural elements (each structural element 12 in the mesh stent may have its own cavity, thus plurality of cavities amongst all the structural elements 12; further, elements 12 are shown to have multiple cavities

Fig. 9, for example; further, at least one cavity is disclosed, encompassing more than one, col. 2, lines 59-61).

Regarding Applicant's Claims 30-37, the Examiner argues that Whicher clearly discloses controlling properties of the material and its microstructure (heterogeneities) by the deposition process (col. 2, lines 6-10 and 16-31; col. 3, lines 17-25; see also Board Decision for related U.S. Application 09/707,685 mailed on September 30, 2008 having a common inventor, same assignee, and same attorney of record in which the Whicher reference was affirmed based on similar claim language). The Examiner argues that Whicher's method inherently controls the stent's heterogeneities because Whicher discloses the same vacuum deposition processes (sputtering, ion beam deposition) and use of the same materials used by the Applicant. The Examiner states that Applicant discloses in its specification that it is the vacuum deposition process that controls the heterogeneities. The Examiner argues since Whicher is using the same process as the applicant, Whicher is inherently "controlling heterogeneities" just as much as the Applicant. The Examiner further argues that Whicher discloses controlling the microstructure (see col. 2, lines 15-32; col. 3, lines 15-25; and Board Decision of related U.S. Application 09/707,685 mailed on September 30, 2008).

7. Argument

In the Examiner's Answer (hereinafter "Answer"), the Examiner addressed Applicant's arguments in the same order and with the same headings as Applicant presented the arguments in Applicant's Appeal Brief (hereinafter "Appeal Brief"). As such, Applicant will address the Examiner's arguments made in the Answer in the same manner. All arguments made by Applicant in the Appeal Brief are incorporated by reference in this Reply Brief. Applicant's failure to restate arguments from the Appeal Brief in this Reply Brief should not be viewed as an abandonment of these arguments.

I. The Examiner's Answer to the Applicant's Appeal Brief to the obviousness rejection of Claim 16 under 35 U.S.C. §103(a) is improper.

A. Brown still fails to disclose a base layer and a second layer as construed by one of ordinary skill in the art

The Examiner alleged that the Board's previous holding in *Ex parte Boyle* that "Brown does not describe a stent with a metal base layer and a second layer also made of metal" (Appeal 2007-3231, p. 13 April 30, 2008) has limited scope and therefore does not prevent the Examiner

from asserting that Brown's element 12 is made of more than one layer. Answer, p. 8. In *Boyle*, the Examiner argued that Brown's element 12 represented a base layer and element 34 represented a second layer (as shown in FIG. 5) or, in another embodiment, that Brown's element 40 represented a base layer and Brown's elements 44 and 49 represented second layers (as shown in FIG. 7). *Id.* at 12. Since the Examiner considered Brown's element 12 to be a single base layer in *Boyle*, the Examiner alleged that the Board's previous holding does not apply to Examiner's instant argument that Brown's element 12 is composed of both a base layer and a second layer, as required by Claim 16.

The Examiner inappropriately limited the scope of the Board's holding that "Brown does not describe a stent with a metal base layer and a second layer also made of metal." *Boyle*, Appeal 2007-3231 at 13. Rather than narrowly holding that Brown's element 12 does not represent a metal base layer and Brown's element 34 does not represent a metal second layer, the Board broadly held that Brown, **as a whole**, "does not describe a stent with metal base layer and a second layer also made of metal." *Id*, emphasis added. As such, the Board's holding applies with equal force to the Examiner's argument in *Boyle* as it does to Examiner's instant argument that element 12 is composed of both a base layer and a second layer. Thus, the Board's previous holding in *Boyle* resolves the issue of whether Brown discloses a base layer and second layer, as required by Claim 16. Nonetheless, Applicant will assume, *arguendo*, that the Board's previous holding is irrelevant and will address the Examiner's arguments directly.

In response to Applicant's argument that Brown's element 12 is not composed of discrete layers (Appeal Brief, p. 8), the Examiner alleged that Claim 16 does not claim discrete layers. Answer, p. 9. Claim 16 requires "**a** base layer and **a** second layer covering the base layer". Emphasis added. Since the base layer and second layer are separate elements of Claim 16, Applicant contends that the base layer and second layer are discrete physical objects. And such a claim construction is necessary to give meaning to the "void space intermediate the base and second layers and enclosed therebetween" limitation of Claim 16. In other words, the layers must be discrete and separate elements (that is, apart or detached from each other) in order to have a void space intermediate and enclosed therebetween. Moreover, Claim 16 requires that the base layer and second layer are "vacuum deposited structural elements"; as such the layers are necessarily discrete when the claims are read in light of the specification and vacuum deposition. The Board is obligated to construe claims broadly as it reasonably can, but the reasonable limits

of that breadth are set by the plain language of the claims and the teachings of the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). On page 11, lines 9-13 of Applicant's specification, vacuum deposition techniques:

> deposit requisite patterns of sacrificial material to form the regions of the internal cavities and openings, over a base layer of structural material, then depositing a second layer of structural material over the sacrificial material and the base layer. The sacrificial material may then be removed, such as by etching, to leave the internal cavities and plurality of openings formed within the deposited bulk material.

Such reading of the Applicant's specification to construe the claim 16 necessarily gives meaning to "a base layer and a second layer covering the base layer" as being discrete and separate elements by virtue of the vacuum deposition process that first deposits a base layer and then deposits a second layer of structural material over a sacrificial material and base layer, and then the sacrificial material is removed to leave "a base layer and a second layer covering the base layer". Indeed, the manufacturing process that the Examiner refers for "layer" in the specification gives meaning and definition to the "base layer" and "second layer". In sum, Claim 16 does claim discrete and separate base and second layers.

Additionally, the Examiner alleged that a base layer and second layer are not described by Applicant's specification; specifically the Examiner argues that a base layer and second layer are not shown in Applicant's FIG. 6. Answer, p. 9. The Applicant notes that the Examiner heavily, inappropriately, and exclusively relies on Applicant's figures to show what "a base layer" and a "second layer" are in the stent. The use of the words in the context of the written description and customarily by those skilled in the relevant art accurately reflects both the "ordinary" and the "customary" meaning of the terms in the claims. *Ferguson Beauregard/Logic Controls v. Mega Systems*, 350 F.3d 1327, 1338, 69 USPQ2d 1001, 1009 (Fed. Cir. 2003); *see also* MPEP §2111.01. On the contrary, the Applicant describes the base layer and second layer in the written description, for example, on page 11, lines 9-13 of Applicant's specification, which Examiner inappropriately ignores for claim construction purposes. There, Applicant describes the use of vacuum deposition techniques to "deposit requisite patterns of sacrificial material to form the regions of the internal cavities and openings, over a base layer of structural material, then depositing a second layer of structural material over the sacrificial material and the base layer. The sacrificial material may then be removed, such as by etching, to leave the internal cavities and plurality of openings formed within the deposited bulk material." Thus, Applicant

adequately describes the base layer and second layer and, furthermore, describes their utility and characteristics in the manufacturing process – that is, providing for the creation of pores and void spaces on the structural member itself. During vacuum deposition, a sacrificial material is first placed on the base layer and then the second layer is placed on top of the sacrificial material (Boyle, p. 11, lines 9-13). Subsequent removal of the sacrificial material from the base and second layers provides for the void space that is intermediate and enclosed therebetween. More so, Claim 16 states that the "vacuum deposited structural elements" are fabricated of a metal and comprise a base layer and a second layer". As such, the base layer and second layer are described by Applicant's specification for proper claim construction purposes.

In a separate argument, the Examiner alleged that a vacuum deposition process of depositing layer upon layer necessarily results in a "final unitary one-piece component", which does not have discrete layers. Answer, p. 9. The Examiner's assumption is unwarranted and unsupported. Merely because the end product of a vacuum deposition process may result in a "one-piece component" does not mean that the individual components produced by vacuum deposition are not composed of discrete layers. For example, in an embodiment where the base layer and the second layer are different materials, it is evident that the base layer and second layer are discrete layers despite the fact that they comprise a "one-piece component". Furthermore, even where the base layer and second layer are the same material, it is reasonable to label them as discrete layers to one of ordinary skill in the art, when a sacrificial layer is deposited over the base layer and the second layer is deposited over the sacrificial material and the base layer, and then sacrificial material is removed. Applicant's specification, p. 11. The Examiner cannot assume that the base layer and the second layer lose their characteristics once the sacrificial material is removed or the second layer collapses to become a single unitary product with the base layer. As such, the base layer and second layer of Claim 16 should be construed as discrete layers.

In another argument, the Examiner alleges that "if appellant's end product is considered to have 'layers,' Brown's end product (as it has the same shape) may also [be] considered to have 'layers'". Answer, p. 9. In construing claim terms, the general meanings gleaned from reference sources, such as dictionaries, must always be compared against the use of the terms in context, and the intrinsic record must always be consulted to identify which of the different possible dictionary meanings is most consistent with the use of the words by the inventor. *ACTV,*

Inc. v. The Walt Disney Company, 346 F.3d 1082, 1092, 68 USPQ2d 1516, 1524 (Fed. Cir. 2003); *see also* MPEP §2111.01. The Examiner disregards Applicant's description of the vacuum deposition process and steps used to form the base layer and second layer (Boyle, p. 11, lines 9-13) for properly construing the claim terms most consistent with the use of the words by the inventor. The reasonable limits of the meaning of Claim 16's "layer" are set by the teachings of the specification and the vacuum deposition techniques known in the microelectronics fabrication arts to be able to deposit separate layers and separate such layers through a sacrificial material. Nowhere does Brown teach the use of vacuum deposition to manufacture tubular member 12. As such, the mere similarity in shape or end product of Brown's stent and Applicant's stent does not render Brown's stent as having discrete and separate layers as one of ordinary skill in the vacuum deposition arts would construe. The Examiner's misconstruction of the claim terms leads the Examiner to inappropriately conclude that Brown's end product (as it has the same shape) may also [be] considered to have 'layers'.

Still further, the Examiner alleged that because Applicant has not labeled with numerals the base layer and second layer in its figures, Applicant's stent is no more composed of layers than Brown's tubular member 12 – which Brown also has not labeled with layers in its figures Answer, p. 9. Once again, the Examiner has disregarded the fact that Applicant describes its stent as being manufactured from a vacuum deposition process whereas Brown does not, and proceeds with a figure-by-figure comparison rather than with a proper claim construction. Claim construction does not require the Applicant to label the layers with numerals and the Applicant is not aware of any court precedent indicating otherwise. Moreover, during patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000) (emphasis added). In order to manufacture Applicant's endoluminal stent, Applicant's specification states that internal cavities and openings can be formed by depositing patterned sacrificial material "over a base layer of structural material, then depositing a second layer of structural material over the sacrificial material and the base layer" and removing the sacrificial material "to leave the internal cavities and plurality of openings." (Spec. page 11, lines 8-13). The Board previously determined this statement to be a "Finding of Fact." *Boyle*, Appeal 2007-3231 at p. 3 (see FF3). Given that a "sacrificial material" is disposed between the base and second layer, it is reasonable to interpret the base layer and second layer as being separate or discrete layers, especially since the

sacrificial material is removed. As such, Applicant's failure to label the base and second layer in its figures does not render them non-existent as the Examiner has implied. Thus, the Examiner has not given Claim 16's base layer and second layer their broadest reasonable interpretation consistent with the specification.

The Examiner continues to rely on an erroneous redrawing of Brown's Figs. 2A, 3, 6, and 8 (as seen in Attachments 2-5) where the Examiner adds a "base layer" and "second layer" to Brown's tubular member 12 to inappropriately reconstruct Claim 16. Answer, pp. 10-11. Applicant recognizes that Brown's Figs. 2A, 3, 6, and 8 each include lines that seemingly separate the tubular member 12 into individual sections. However, these are cross-sectional lines for purposes of displaying a cross-section of a single unitary piece of material, Brown does not label any of the individual sections formed by these lines, nor does Brown describe the tubular member 12 as having individual sections in its written description. One of ordinary skill in the art immediately recognizes that the lines in Brown's Figs. 2A, 3, 6, and 8 are "sectional lines" commonly used by draftsmen to denote that a cross-sectional view is being shown (this drafting technique is also known as "hatching"). Brown's Figs. 2A, 3, 6, and 8 are described in the "BRIEF DESCRIPTION OF THE DRAWINGS" as being "sectional" or "cross-sectional views," which supports the view that the lines are sectional lines. Even if these lines are not considered "sectional lines," the Examiner, in hindsight, inappropriately groups several sections together and labels them as a base layer or a second layer. For example, in the Examiner's redrawing of Brown's Fig. 6 in Attachment 3 (reproduced previously), the Examiner arbitrarily shades three of the sections of tubular member 12 and labels them as the second layer and then labels the remaining four section as the base layer. Any redrawing of Brown's Figures does not reach or teach the base layer and the second layer covering the base layer, by vacuum deposition or otherwise. The Examiner's reliance on the drawings leads to the Examiner's misconstruction of the claims. The Examiner alleges that "the figures alone provide support for layers". Answer, p. 9. And for this reason, the Examiner only construes the figures while not properly construing the claim language.

Still further, Brown implicitly describes the tubular or elongated member 12 as being formed from a single, continuous material so as to not include a separate discrete base layer and second layer, as follows:

> The elongated member 12 is preferably formed of **a** fairly rigid, impermeable, and strong material which is non-biodegradable. The elongated member material is preferably **a** biocompatible metal or alloy such as stainless steel, titanium, platinum, tantalum, silver, tungsten, gold, and their alloys as well as gold-plated ferrous alloys, platinum-plated ferrous alloys, cobalt-chromium alloys and titanium nitride coated stainless steel. Alternatively, the elongated or tubular member 12 may be formed of **a** polymer, such as polyether sulfone, polyamide, polycarbonate, polypropylene, high molecular weight polyethylene, carbon fiber, and the like.

Brown, col. 7, lines 12-21 (emphasis added). Brown's reference to the composition of the elongated or tubular member 12 clearly indicates that it is **a** singular, continuous substance. And while the cross-section may be oval, elliptical, octagonal, or square, the tubular member 12 will still remain a **single** "strand, filament, or fiber" (Brown, col. 5, lines 65-67), and nothing more. Thus, the Examiner's redrawing of Brown's Fig. 6 in attachment 3 is arbitrary and unwarranted and the Examiner's alteration of Brown's Figs. 2A, 3, 6, and 8 to include a base and second layer is unwarranted and improper. For at least these reasons, the Applicant submits that Brown still fails to disclose a base layer and a second layer.

B. Alternatively, Brown still fails to disclose a void space intermediate the base and second layers that is enclosed therebetween

The Examiner alleged that Brown is considered by the Examiner to contain a void space (cavity 20) intermediate the two layers (18, 19; see attachments 2-5, previously reproduced). Answer, p. 12. Again, the Applicant maintains that 18 is the luminal portion of Brown's stent and for contacting the interior of the body lumen and 19 is a support portion for supporting the walls 14 of the body lumen 13, which may be an exemplary blood vessel. Brown, Col. 6, lines 26-34. Any cavity 20 of Brown is not a void space intermediate the base and second layers, as Fig. 2A shows the cavity 20 not enclosed therebetween the luminal portion 18 or support portion 19, as cavity 20 of Brown is a concave groove extending along the entire length of the elongated member 12. Brown, Col. 5, lines 49-51. Presumably, the concave groove 20 is open throughout the entire length nor closed off at any portion of Fig. 2a. Any discontinuous voids disclosed and argued by the Examiner (Answer at p. 12) would still be a concave groove and not intermediate and enclosed therebetween.

The Examiner alleged that "[t]he void is not required to be centered, it is only required to be positioned in between the base and second layer, which Brown's void (20) is [, and] [i]ntermediate is defined as positioned in between two points, not in the middle or centered as appellant has inferred". Answer, pp. 12-13. On the contrary, the void space is "intermediate the

base and second layers that is enclosed therebetween". "Therebetween" already defines the void space in between the base layer and the second layer, while "intermediate" positions the void space at or occurring at the middle point between the base layer and second layer. "Intermediate" is defined as "being or occurring at the middle place, stage, or degree or between extremes". At http://www.merriam-webster.com/netdict/intermediate, last accessed April 19, 2010. The Examiner has misconstrued the void space intermediate the base and second layers that is enclosed therebetween. Consequently, Brown still fails to disclose a void space intermediate the base and second layers that is enclosed therebetween.

C. Brown is still not combinable with Whicher, since the Examiner has provided no reason that Whicher is combinable with Brown (no reason that vacuum deposition would be combinable with the stent of Brown).

The Examiner alleged that Brown does not disclose any methods of manufacture of the stent structural elements of figures 3-10 and disclosed mesh stent of Col. 7, lines 33-40. Answer p. 13. The Examiner alleged that "Brown briefly discloses one way to make a stent according to a different embodiment (figs. 13- 18; col. 11, lines 62-67) which it is unclear if this method also applies to the embodiment used in the rejection, however since it is the only method disclosed, it may be assumed it applies". Answer p. 13. The Applicant respectfully disagrees. The embodiment disclosed by Brown and it's method of manufacturing is to form a groove 120 on the exterior surface of the tube 102, where a laser defines a groove having a concave shape when viewed in the cross-section. Brown, Col. 12, lines 14-25, Figs. 13-18. Once the groove 120 has been filled with an active agent 123, a plurality of perforations, slits, or slots are formed in the tube 102 to extend completely through the tubular member thickness and preferably with a laser to allow the stent 111 to be expanded. Brown Col. 12, line 61-Col. 12, line 11, Figs. 17-18. Brown's method of manufacturing the groove portion 120 is only for the embodiment in Fig. 2a, and the Examiner incorrectly assumes that the method of manufacturing applies to any embodiments of Figs. 5-6. Brown does not teach or disclose any method of manufacturing for Fig. 6, which the Examiner heavily relies upon. As such, it is incorrect to assume that the method disclosed by Brown applies to all embodiments disclosed in Brown.

The Examiner alleged that Brown acknowledges that other methods not disclosed are feasible and such acknowledgment does not teach away from alternative methods of manufacture. Answer, p. 13. This citation of Brown or other conventional methods, cited by the Examiner is an insufficient rationale or reasoning for a rejection based on §103(a). A statement

that modifications of the prior art to meet the claimed invention would have been "'well within the ordinary skill of the art at the time the claimed invention was made'", because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). The methods not disclosed in Brown do not fall well within the ordinary skill in the art, and something that is not present cannot provide for alternative methods of manufacture. The Examiner reaches for a method of manufacturing not present; however, the alternative methods of manufacturing are simply not present or fairly suggested.

Moreover, the Examiner alleged that Brown disclosed laser cut or etching the cavities/void space. Answer, pl. 13. The Applicant notes that Brown does not teach or suggest any etching methods, such as chemical etching with an acid or photo-etching by a photo-sensitive coating. The Applicant respectfully submits the Board to ignore such statement or teachings of Brown.

And the Applicant respectfully disagrees with the Examiner use of the Applicant's own specification for vacuum deposition as an alternative for laser cutting/etching as evidence that one is obvious alternative to the other. The Examiner cites to Applicant's specification p. 10-11; however, the Applicant notes that the specification at p. 10-11 is the Applicant's "Detailed Description of the Preferred Embodiments" and is no admission of prior art or the general teachings of one of ordinary skill in the art. The Examiner must determine whether the subject matter identified as "prior art" is applicant's own work, or the work of another. § MPEP 2129. Nothing is admitted as prior art in the Applicant's Detailed Description and it is Applicant's own work. The Applicant respectfully submits to the Board to ignore such statements or characterizations by the Examiner using the Applicant's own specification as alternative methods of manufacturing for laser cutting.

For at least these reasons, the Applicant submits that Brown is still not combinable with Whicher, since the Examiner has provided no reason that Whicher is combinable with Brown (no reason that vacuum deposition would be combinable with the stent of Brown).

D. Brown in view of Whicher would not have provided a predictable construct (final product), that is Whicher does not disclose the process steps during vacuum deposition that the appellant uses and Whicher does not disclose how to create a stent with voids.

The Examiner alleged that particular process parameters (temperature, pressure, etc.) have not been claimed, thus are not required by Whicher. Answer p. 14. On the contrary, the process parameters and process steps are necessary to enable one of ordinary skill in the art to arrive at the construct the Examiner proposes, and any combination of Brown and Whicher does not enable one of ordinary skill in the art to form a vacuum deposited structural element comprising a base layer and a second layer covering the base layer, further comprising a void space intermediate the base and second layers that is enclosed therebetween. As indicated previously, Brown only teaches a method of manufacturing a groove into a tube stent and laser cutting slots to make the tube expandable. Whicher only teaches forming a single metallic layer on a substrate and removing that metallic layer from the substrate. The substrates and deposition steps in Whicher provide a single unitary construct, but does not teach or suggest the modification or vacuum deposition steps necessary for the base layer, the second layer, and the void space therebetween. The vacuum deposition steps necessary for the base layer, the second layer, and the void space therebetween is provided in Applicant's specification, i.e. "the internal cavities and openings must be formed during deposition, the vacuum deposition techniques must be modified to deposit requisite patterns of sacrificial material, to form the regions of the internal cavities and openings, over a base layer of structured material, then depositing a second layer of structured material over the sacrificial material and the base layer". Applicant's specification, p. 11, lines 8-12. Whicher is silent to any sacrificial material, Brown is silent as to any method steps or process parameters to reach any elements of Claim 16 or the embodiment of Fig. 6, thus, any combination of Brown's teachings with Whicher teachings merely arrive at a stent structure 100 or 200 as disclosed in Whicher that may be laser cut with grooves 120 of Brown—at most, this is merely a mesh stent structure, not a "a vacuum deposited structural element comprising a base layer and a second layer covering the base layer" and "a plurality of pores passing through the second layer and communicating with the void space such that the void space is open only through the plurality of pores", as required by Claim 16.

The Examiner alleged that "[v]acuum deposition is a product by process limitation. Answer, p. 14. First, the Applicant claims "vacuum deposited structural elements" that comprise a base layer and a second layer covering the base layer", thus the base layer and the second layer necessarily are a vacuum deposited structural element, which obviates any product-by-process limitation the Examiner alleged. Secondly, even if the vacuum deposition is a product by

process limitation, there are unobvious differences in the claimed invention. Once the Examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi,* 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983). Whicher does not enable the formation of a base layer and a second layer covering the base layer, and it is unobvious because Brown only teaches forming a grooved cavity in a stent structuring by laser cutting, nothing which makes it obvious to take any structure in Brown and form or arrive at applicant's claimed invention. It is unobvious that the "the internal cavities and openings must be formed during deposition, the vacuum deposition techniques must be modified to deposit requisite patterns of sacrificial material, to form the regions of the internal cavities and openings, over a base layer of structured material, then depositing a second layer of structured material over the sacrificial material and the base layer". Applicant's specification, p. 11, lines 8-12. Any formation of the internal cavities or void spaces intermediate the base layer and the second layer after deposition would not form a structurally sound or operable stent structure for delivering a bioactive agent. Whicher's teaching does not cure this deficiency in Brown by any suggestion to one of ordinary skill in the art, as Whicher only teaches depositing single layers. As such, any product-by-process limitation in Claim 16 includes unobvious differences from Brown and Whicher by virtue of the vacuum deposition process disclosed by the Applicant.

And the Examiner alleged that "[a]s appellant's specification (929' incorp. by reference) admits, it is known and standard vacuum deposition processes that are used with the invention (no specific parameters are disclosed to make the method special or different), thus the fact that Whicher teaches vacuum deposition on stents is enough". Answer, p. 14. The examiner must determine whether the subject matter identified as "prior art" is applicant's own work, or the work of another. §MPEP 2129. The Applicant vehemently objects to the Examiner using the Applicant's own specification for rationale and reasoning to one of ordinary skill in the art, and the Examiner's use of Applicant's own specification is the best example of hindsight reasoning by the Examiner. The Applicant respectfully requests the Board to ignore the Examiner's use of the Applicant's own specification to support the Examiner's §103(a) reasoning or rationale. Moreover, any teaching of vacuum deposition is not enough for one of ordinary skill in the art,

and specific parameters and deposition steps are disclosed to make the method and claims unobvious over Brown and Whicher.

The Examiner alleged that Whicher is used only as a teaching of method manufacture (how to configure the metal). Answer, p. 14. However, merely because Whicher teaches vacuum deposition is not enough, one of ordinary skill in the art still needs to arrive at any final structure the Examiner proposes. Brown teaches of braiding wires, welding them together or laser cutting a tube and the cavities may be formed by further cutting. Again, this is not enough and inadequate to arrive at a base layer and a second layer covering the base layer further comprising a void space intermediate the base layer and second layer that is enclosed therebetween and a plurality of pores passing through the second layer and communicating with the void space. The Examiner alleged that Whicher teaches vacuum deposition as an obvious alternative to braiding/welding wires and laser cutting tubes. Answer, p. 15. Such teaching is insufficient, because it does not teach or enable one of ordinary skill in the art to arrive at any structure in Brown, and in fact, specific vacuum deposition steps are required, i.e. "internal cavities and openings must be formed during deposition, the vacuum deposition techniques must be modified to deposit requisite patterns of sacrificial material, to form the regions of the internal cavities and openings, over a base layer of structured material, then depositing a second layer of structured material over the sacrificial material and the base layer". Applicant's specification, p. 11, lines 8-12. Consequently, Whicher's teaching of the method manufacture does not teach such deposition steps and does not teach how to configure the metal to arrive at Applicant's claimed invention in Claim 16.

Additionally, the Examiner alleged that Whicher teaches making complex geometries including the use of patterns, mask, release layers, multiple metal layers, etc. citing to Fig. 6b and col. 7, line 57-col. 9, line 65 of Whicher, wherein multiple layers are disclosed to be deposited which may be subjected to machining after deposition-thus the cavities may be cut out after deposition, leaving a stent whose structural elements are vacuum deposited), thus encompassing and within the realm of Browns stent. Answer, p. 15. Such teaching by Whicher still does not arrive or enable a base layer and a second layer covering the base layer further comprising a void space intermediate the base layer and second layer that is enclosed therebetween and a plurality of pores passing through the second layer and communicating with the void space. Any release layer 140 by Whicher is applied to the mandrel 105 and is for the

purposes of releasing the metallic layer 115 from the mandrel by dissolving the release layer 130 while not affecting the mandrel 105 or the metallic layer 115 and not for the purposes of forming a base layer and a second layer covering the base layer further comprising a void space intermediate the base layer and second layer. Whicher Col. 7, lines 57-67. Any pattern disclosed by Whicher is form a pattern of openings 101 in a slotted metallic stent to help facilitate expansion for deployment, not for a void space intermediate the base layer and second layer. Whicher, Col. 8, lines 7-14. Any mask taught by Whicher is for the purpose and enabling of forming the openings 101 or 210 to result in a slotted metallic stent 100 or wire-formed metallic stent 200, and not for a base layer and a second layer covering the base layer further comprising a void space intermediate the base layer and second layer. Whicher, Col. 8, lines 14-23, Figs. 9 and 10. And any multiple layers 116 or 117 are deposited on top of metallic layer 115 and are a radiopaque material to impart radiopacity to the medical device or a material, such as carbon, to impart thrombogenicity and corrosion and/or fatigue resistance to the medical device, the layers do not form a second layer covering the base layer and a void space intermediate the base layer and second layer. Whicher, Col. 9, lines 35-45. Even if the multiple layers 116 or 117 are subjected to machining after deposition, the laser cutting would still just form a single groove structure without a second layer covering the base layer to form a void space intermediate the base layer and the second layer. The Examiner's argument for enablement of Whicher still comes up short of encompassing Browns stent and Applicant's claimed invention.

The Examiner alleged that "even appellant's specification notes that either braiding wires and welding them together, or laser cutting tubes may be used or alternately, vacuum deposition (pg. 10-11), thus appellant evidences that one is an obvious alternative to the other". Answer, p. 15. Again, the Applicant vehemently objects to the Examiner using the Applicant's Detailed Description of the Preferred Embodiments for any rationale or reasoning by the Examiner to form the basis of the §103(a) rejection. The Applicant respectfully requests the Board to ignore such statements by the Examiner.

And the Examiner alleged that "a solid stent may be vacuum deposited and then the pores/voids formed after deposition (by laser cutting or etching out the pores)". Answer, p. 15. First, the Examiner's proposal would merely create a stent structure with pores and not a stent structure with a void space intermediate the base and second layer and communicating with the pores. Second, the Examiner is proposing to laser cut cavities into the deposited stent structure of

Whicher and then laser cut or etch out a plurality of pores passing through the second layer and communicating with the void space such that the void space is open only through the plurality of pores. No guidelines or parameters are provided for such a hypothetical construct in either Whicher or Brown, and more so, highly unpredictable to one of ordinary skill in the art in deposition and stent technologies. Only portions of the metallic layer 115 not intended to be part of the stent 100, i.e. stent struts, are suggested to be removed by, machining, etching, laser cutting and the like to form a medical device or a member of a medical device. Whicher, Col. 8, lines 36-40, Fig. 13. Whicher only teaches forming the struts of the stent in a positive or negative pattern 170 and 160, nothing to teach or enable one of ordinary skill in the art to form pores/voids, and more so, a void space intermediate the base and second layer.

For at least these reasons, the Applicant submits that Brown in view of Whicher still would not have provided a predictable construct (final product), that is Whicher does not disclose the process parameters during vacuum deposition that the appellant uses and Whicher does not disclose how to create a stent with voids. Consequently, the Examiner's Answer to the Applicant's Appeal Brief to the obviousness rejection of Claim 16 under 35 U.S.C. §103(a) is still improper.

II. The Examiner's Answer to the Applicant's Appeal Brief on the obviousness rejection of Claim 20 under 35 U.S.C. §103(a) is improper.

The Examiner alleged that "[a]ctive agent 23 may be carried in a delivery matrix 27 which is a degradable polymer, as the polymer degrades, active agent is released out of the pores, and as the matrix 27 degrades, particles/pieces of the matrix 27 break apart and move through the pores to exit the stent. Answer, p. 16. The delivery matrix 27 is located within the cavity or interior and the cavity 20 contains the delivery matrix 27. Brown, Col. 3, lines 21-24, Col. 8, lines 62-64, fig. 4. The delivery matrix 27 upon dissolution as the Examiner contends, is not residing within the plurality of pores to prohibit release of the bioactive agent until the degradation of the degradable plug. When delivery matrix 27 degrades, breaks apart, and moves through the pores to exit the stent as the Examiner contends, the delivery matrix in Brown does just that, breaks apart and moves through the slit opening 22 and does not reside within the slit opening to prohibit release of the bioactive agent until the degradation.

The Examiner alleged that some of the bioactive agents 23 themselves are degradable (collagen, elastin, etc. col. 5, lines 1-27) and are shown located in the pores (fig.3, 9, and 10), thus themselves may be considered a degradable plug, as multiple active agents in combination

are disclosed.. Answer, p. 16. The Applicant notes that a degradable plug as claimed in Claim 20 is a separate element from the at least one bioactive agent, and notably, the degradable plug includes a different location than the bioactive agent. The mere fact that a bioactive agent is degradable ignores the requirement and limitation that the degradable plug resides within the plurality of pores and prohibit release of the at least one bioactive agent until the degradation of the degradable plug. Indeed, none of the bioactive agents cited by the Examiner reside within the plurality of pores, nor are they shown to prohibit the release of the bioactive agent until the degradation of the degradable plug. The Examiner stretches to render Claim 20 obvious and the Examiner's technical reasoning is weak at best. Mostly, the Examiner does not show or enable how any of the multiple active agents in combination disclosed Brown meet the limitations of Claim 20. Consequently, the Examiner's Answer to the Applicant's Appeal Brief on the obviousness rejection of Claim 20 under 35 U.S.C. §103(a) is improper.

III. The Examiner's Answer to the Applicant's Appeal Brief on the obviousness rejection of Claim 26-27 under 35 U.S.C. §103(a) is improper.

While the specifically claimed elements in each of Claims 26 and 27 are broader than the specific disclosure in the Brown or Whicher reference, Applicant acknowledges that if any element of a Markush claim is anticipated, then the entire claim is considered anticipated. *Ecolochem, Inc. v. Southern California Edison Co.*, 91 F.3d 169 (Fed. Cir. 1996); *In re Skoll*, 523 F.2d 1392, 1397, 187 USPQ 481, 484-85 (C.C.P.A. 1975). Since Claims 26 and 27 are framed as Markush claims, the patentability of Claims 26-27 are based upon the patentability of independent Claim 16, as discussed above. Accordingly, the Examiner's Answer to the Applicant's Appeal Brief on the obviousness rejection of Claim 26-27 under 35 U.S.C. §103(a) is improper.

IV. The Examiner's Answer to the Applicant's Appeal Brief on the obviousness rejection of Claim 28 under 35 U.S.C. §103(a) is improper.

The Examiner alleged that "[e]ach structural element making up the disclosed mesh stent of Brown (struts 12 of stent disclosed co1.7, lines 34-40) may have its own single cavity, thus making up a plurality of cavities amongst the plurality of structural element. Answer, p. 16-17. Claim 28 requires that the "void space comprises a plurality of independent cavities along the length of the structural elements" (underline added), not for the structural elements of Brown to include a plurality of cavities. Each single cavity of Brown on the mesh stent is a single cavity

and does not further include a plurality of independent cavities. The claim does not read "the structural elements comprise a plurality of independent internal cavities", as the Examiner appears to be construing.

Alternatively, the Examiner alleged the "one embodiment shows a single structural element (12; fig.9) having two parallel cavities that are independent". Answer, p. 17. Again, Fig. 9 does not cure the deficiencies of the Examiner's claim construction of Claim 28. Claim 28 requires that the void space comprise a plurality of independent internal cavities, and Fig. 9 shows that the elongated member 72 that includes two cavities 20, nothing indicates that the two cavities are independent or within a single void space.

Alternatively, the Examiner alleged that Brown discloses a structural element (12) to comprise at least one cavity (col. 2, lines 59-61), thus encompassing more than one cavity per structural element. Answer, p. 17. Again, the void space comprises a plurality of independent cavities, and any structural element of Brown encompassing more than one cavity per structural element does teach or fairly suggest a void space comprises a plurality of independent cavities. The Examiner has interpreted independent internal cavity to mean "separate, distinct and individual positioning". Answer, p. 17. Taking the Examiner's interpretation of independent internal cavity, then the void space of Claim 28 comprises a plurality of separate, distinct, and individual positioned cavities, which Brown does not teach nor fairly suggest. Consequently, a structural element 12 by Brown including more than one cavity per structural element does not teach or disclose a void space comprising a plurality of independent cavities.

For at least these reasons, the Examiner's Answer to the Applicant's Appeal Brief on the obviousness rejection of Claim 28 under 35 U.S.C. §103(a) is still improper.

V. The Examiner's Answer to the Applicant's Appeal Brief on the obviousness rejection of Claim 30 under 35 U.S.C. §103(a) is improper.

The Examiner alleged that "heterogeneities of grain size, grain phase, grain material composition, surface topography (supported by pg.8 of 929') are admitted in the 929' to be inherently present and inherently controlled and optimized by the vacuum deposition process (see pg. 9-10 of 929' vacuum deposition) yields a metal having controlled heterogeneities, the vacuum deposition suitable for use being those known and standard in the microelectronics art, "the foregoing properties are achieved by fabricating a stent by the same metal deposition methodologies as are used and standard in the microelectronics and coating arts")". Answer, pp.

17-18. First, the Applicant objects to the Examiner using the 929' application to support any rationale or reasoning that heterogeneities are inherently present and controlled and optimized by the vacuum deposition process. If the Examiner is using the 929' application to support a §103(a) rejection, then the Examiner should have done so when making out a prima facie case of obvious. And if so, the 929' application is a commonly owned and assigned application and would be properly removed from consideration as a 102(e) reference. *See* MPEP §2146 "subject matter which was prior art under former 35 U.S.C. §103 via 35 U.S.C. §102(e) is disqualified as prior art against the claimed invention if that subject matter and the claimed invention "were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person". Both the 929' application and the present application are assigned to Advanced Bio Prosthetic Surfaces, Ltd. Reel/Frame 013835/0159 for the 929' application and Reel/Frame No. 011702/0340 for the present application.

Secondly, the Examiner is using the elements and limitations from dependent Claim 31 to support the statement that controlled heterogeneities consist of grain size, grain phase, grain material composition, surface topography. Specifically, dependent Claim 30 states "the metal of the first and second layers has at least one surface thereof having controlled heterogeneities". The Applicant respectfully notes that the Examiner has read the limitations of dependent Claim 31 into dependent Claim 30. Nothing in Whicher indicates that the first and second layers have at least one surface thereof having controlled heterogeneities. Whicher deposits metallic layer 115 and optionally coats metallic layer 116 with a layer 116 of radiopaque material or optionally coats metallic layer 115 with a carbon material. Whicher, Col. 9, lines 35-43. Any layer 115, 116, 117 of Whicher is coated on top each other, and presumably any surface of 115, 116, or 117 coated on top each other would only have a single surface at which any microstructure the Examiner assumes to be controlled, not a first and a second layer having controlled heterogeneities one at least one surface thereof.

However, even if the Examiner is properly using the 929' application to support her reasoning and rationale for the §103(a) rejection of Claim 30, the Examiner's rationale that vacuum deposition processes inherently control and present controlled heterogeneities is far reaching and legally insufficient. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). "In relying upon the

theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). The Examiner provides no facts and/or technical reasoning to reasonably support the determination that controlled heterogeneities selected from the group consisting of grain size, grain phase, grain material composition and surface topography necessarily flows from pg. 9-10 of the application, and Examiner conveniently ignores the rest of the 929' application that further discuss and provide examples of controlled heterogeneities on the surface of the deposited metal and the process steps to achieve such controlled heterogeneities versus other material properties.

The Examiner alleged that "Whicher clearly discloses controlling properties of the material and its microstructure (heterogeneities) by the deposition process (col. 2, lines 6-10, 16-31; col.3, lines 17-25, controls composition, surface roughness, microstructure). Answer, p. 18. Again, this does not teach or enable a vacuum deposition process that deposits controlled heterogeneities on the surface of the deposited metal, as Whicher deposits metal onto a mandrel 105, which itself does not have controlled heterogeneities, thus it remains to be seen or proven how the resulting metallic layer 115 of Whicher could have controlled heterogeneities on the surface of the deposited metal. The Examiner cites to open ended statements in Whicher for controlling microstructure, Whicher col. 2, lines 6-10, 16-31; col. 3, lines 17-25; however, such open ended statements do not teach or enable specific process parameters or steps to achieve controlled heterogeneities on the surface of the deposited metal. And any microstructures or grain sizes that may be established by Whicher's deposition parameters are directed to and "affect the mechanical properties such as strength and corrosion resistance". Whicher, Col. 1, lines 10-13, Col. 5, lines 60-63, Col. 9, lines 31-33. Such mechanical properties have little if any do with the controlled heterogeneities on the surface of the deposited metal. In stark contrast, the controlled heterogeneities of Claim 30 and the 929' application are along at least one surface that is along the blood flow surface of the stent having optimal protein binding capability for blood protein interaction to lead to tissue incorporation of the endovascular stent or endothelialization. 929' application, pp. 7-8. Nothing in Whicher speaks to or enables for optimal protein binding capability for blood protein interaction to lead to tissue incorporation of the endovascular stent on the surface of the deposited metals or controlled heterogeneities thereupon. The present

application's working example of sputtering notes that the deposited metal "exhibits material properties similar to the bulk stainless steel target and surface properties characterized by controlled heterogeneities". 929' application, p. 13, underlined added. Specifically, the controlled heterogeneities are on the surface of the deposited metal, while Whicher only references microstructure that relates to the mechanical properties of the deposited metal and nothing to the surface properties. Therefore, Whicher clearly does not disclose controlling properties of the surface or heterogeneities.

The Examiner alleged that Board decision (Appeal 2008-1316) for related application 09/707,685 ("the '685 application) mailed on September 30, 2008 (common inventor, same assignee and same attorney of record) in which the Whicher reference was affirmed based on similar claim language. Answer, p. 18. Again, the Board held that Whicher's vacuum deposition process inherently controlled the formation of precipitates. Appeal 2008-1316, p. 11, attached herewith. Controlling the formation of precipitates is different and separate from controlled heterogeneities on the surface of a deposited metal and the Appeal 2008-1316 appeared to base their reasoning and rationale on the '685 application disclosing no working examples or specific vacuum deposition conditions are described in the Specification. The Applicant noted previously the extensive working examples and conditions for controlled heterogeneities on the surface of the deposited metal in the present application and further below.

The Examiner alleged that "Whicher discloses a method of vacuum deposition (i.e. sputtering, the same technique used by appellant; co1.3, lines 51-60) inherently controls the stents heterogeneities, because Whicher discloses the same vacuum deposition processes (sputtering, ion beam deposition) and use of the same materials used by the appellant". Answer, p. 18. The Examiner's circular reasoning does not get to the details and specifics needed to support an inherency rejection or rationale. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Any sputtering process will not inherently deposit controlled heterogeneities on the surface of a metal, and the Examiner conveniently ignores the unobvious differences disclosed in the 929' application. Page 12, line 19 through Page 13, line 17. "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. The unobvious differences in the present application vs. Whicher's deposition

parameters and steps were noting in Applicant's Brief and also include a ceramic substrate with capabilities of glow discharge cleaning, glow discharge cleaning the ceramic substrate, the deposition sources are circumferential and oriented to deposit from the target circumferentially about the substrate, and sacrificial carbon layer of substantially uniform thickness. Notably, Whicher uses a steel wire mandrel in every example of vacuum deposition (Whicher, Examples 1-5), where the deposited metal on the steel wire mandrel will inherit all the uncontrolled heterogeneities on the surface of the steel wire mandrel.

The Examiner alleged that "Appellants disclose in their specification that it is the vacuum deposition process that controls the heterogeneities", the "appellant's specification (incorporated 929') admits that it is the use of vacuum deposition that controls heterogeneities (see above). Answer, p. 18-19. Again, the Applicant vehemently objects to the Examiner using the Applicant's own specification or the 929' application incorporated by reference, which are commonly owned and assigned, and is not prior art or available as evidence for the Examiner's position of obviousness under §103(a). The Examiner must determine whether the subject matter identified as "prior art" is applicant's own work, or the work of another. §MPEP 2129. The Applicant incorporated by reference the 929' application in the Detailed Description of the Preferred Embodiments of the Invention is Applicant's own work and not work of another, and the Applicant respectfully requests the Board to refrain to considering any labeling in the Applicant's own Detailed Description and in the '929 application as prior art or evidence for the Examiner's contentions. Largely, a majority of the Examiner's argument for the inherency of Whicher fails due to the Examiner's reliance on Applicant's own specification and application incorporated by reference.

And the Examiner alleged that "Whicher teaches a method of manufacturing an endoluminal stent (100) having a plurality of first and second structural elements (see interconnected struts in fig.2 or 3 for example) made by vacuum deposition (vacuum deposition is a form of vapor deposition, specifically sputtering and ion beam deposition processes used within a vacuum chamber, which are the same type of vacuum deposition processes used by the appellant, are disclosed by Whicher, co1.3 lines 51-60)". Answer, pp. 18-19. While Whicher discloses sputtering and ion beam deposition, such deposition processes are not the same variety of vacuum deposition processes used by the Applicant. The Applicant notes that the 929'

application discloses and teaches specific and different sputtering deposition parameters for the controlled heterogeneities on the surface of the deposited material, i.e.:

> A ceramic cylindrical substrate is introduced into a deposition chamber with capabilities of glow discharge substrate cleaning and sputter deposition of carbon and stainless steel. The deposition chamber is evacuated to a pressure less than or equal to $2x10^{-7}$ Torr. Pre-cleaning of the substrate is conducted under vacuum by glow discharge. The substrate temperature is controlled to achieve a temperature between about 300 and 1100 degrees Centigrade. A bias voltage between-1000 and +1000 volts is applied to the substrate sufficient to cause energetic species arriving at the surface of the substrate to have a hyperthermal energy between 0.1 eV and about 700 eV, preferably between 5-50 eV. The deposition sources are circumferential and are oriented to deposit from the target circumferentially about the substrate.
>
> During deposition, the deposition pressure is maintained between 0.1 and 10 mTorr. A sacrificial carbon layer of substantially uniform thickness (+/-5%) between 10 and 500 Angstroms is deposited circumferentially on the substrate. After depositing the carbon layer, a cylindrical film of stainless steel is deposited onto the sacrificial carbon layer on the cylindrical substrate at a deposition rate between about 10 to 100 microns/hour. After formation of the stainless steel film, the substrate is removed from the deposition chamber and heated to volatilize the intermediate sacrificial carbon layer between the substrate and the film. After removing the carbon intermediate layer, the stainless steel film is removed from the substrate and exhibits material properties similar to the bulk stainless steel target and surface properties characterized by controlled heterogeneities in grain size, material composition and surface topography.

929' application, Page 12, line 19 through Page 13, line 17. Whicher does not disclose the same or even similar sputtering deposition processes—it is not a one-to-one comparison as the Examiner alleged. The Examiner alleged that Whicher discloses selection of a temperature, pressure, and rate during deposition; therefore, inherently the precipitates are being controlled, since amount, size, and form of the grains and surface topography are dependent upon temperature, pressure, and rate. The Examiner's circular reasoning ignores other significant steps in the Applicant's deposition process including the ceramic substrate with capabilities of glow discharge cleaning, glow discharge cleaning the ceramic substrate, the deposition sources are circumferential and oriented to deposit from the target circumferentially about the substrate, and sacrificial carbon layer of substantially uniform thickness. Whicher does not disclose any ceramic substrate, glow discharge precleaning of the ceramic substrate, the deposition source is not circumferential in relation to the mandrel (Fig. 4A), and the release layer 130 in Whicher is copper. Any process conditions for controlling heterogeneities on the surface of the deposited

metal are remarkably different and distinct from Whicher and the processes and any conditions selected in Whicher provide no specificity or predictability that the resultant product would have controlled heterogeneities on the surface of the deposited metal as determined by one of ordinary skill in the art.

Most importantly, Whicher does not teach or fairly suggest that the metal of the first and second layers has at least one surface thereof having controlled heterogeneities to render Claim 30 obvious. Whicher discloses depositing either a single metallic layer 115 or coating the metallic layer 115 with a radiopaque material 116 or carbon layer 117 for fatigue resistance. Each layer 115, 116, or 117 would have the same uncontrolled heterogeneities as the layer beneath it. No modifications or altering of process parameters would achieve controlled heterogeneities on at least a surface for the first and second layers wherein a void space is intermediate the first and second layers.

For at least these reasons, the Examiner's Answer to the Applicant's Appeal Brief on the obviousness rejection of Claim 28 under 35 U.S.C. §103(a) is improper.

Summary

The Applicant respectfully solicits the Board to reverse the Examiner's rejections and allow Claims 16, 20, 26-28.

Respectfully submitted,

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8. Claims Appendix

The following is a listing of the claims on appeal.

Claim 16. An endoluminal stent for delivering a bioactive agent to a situs in a body, comprising:

a plurality of vacuum deposited structural elements forming a radially expandable cylindrical member, the plurality of structural vacuum deposited elements including a complex finished geometry, each of the plurality of vacuum deposited structural elements having a wall thickness; wherein the vacuum deposited structural elements are fabricated of a metal and comprise a base layer and a second layer covering the base layer, further comprising a void space intermediate the base and second layers that is enclosed therebetween;

a plurality of pores passing through the second layer and communicating with the void space such that the void space is open only through the plurality of pores; and

at least one bioactive agent retained within the void space and elutable through the plurality of pores.

Claim 20. The endoluminal stent according to claim 16, further comprising a degradable plug residing within the plurality of pores to prohibit release of the at least one bioactive agent until the degradation of the degradable plug.

Claim 26. The endoluminal stent according to claim 16, wherein the metal is selected from the group consisting of titanium, vanadium, aluminum, nickel, tantalum, zirconium, chromium, silver, gold, silicon, magnesium, niobium, scandium, platinum, cobalt, palladium, manganese, molybdenum and alloys thereof, including zirconium-titanium-tantalum alloys, nitinol, and stainless steel.

Claim 27. The endoluminal stent according to claim 16, wherein the bioactive agent further comprises a pharmacologically active agent selected from the group consisting of antibiotic drugs, antiviral drugs, neoplastic agents, steroids, fibronectin, anti-clotting drugs, anti-platelet function drugs, drugs which prevent smooth muscle cell growth on inner surface wall of vessel, heparin, heparin fragments, aspirin, coumadin, tissue plasminogen activator, urokinase, hirudin, streptokinase, antiproliferatives, methotrexate, cisplatin, fluorouracil, adriamycin, antioxidants, ascorbic acid, beta carotene, vitamin E, antimetabolites, thromboxane inhibitors, non-steroidal and steroidal anti-inflammatory drugs, immunosuppresents, such as rapomycin, beta and calcium channel blockers, genetic materials including DNA and RNA fragments, complete expression genes, antibodies, lymphokines, growth factors, vascular endothelial growth factor and fibroblast growth factor, prostaglandins, leukotrienes, laminin, elastin, collagen, nitric oxide, and integrins.

Claim 28. The endoluminal stent according to claim 16, wherein the void space comprises a plurality of independent internal cavities along the length of the structural elements.

Claim 30. The endoluminal stent according to claim 16, wherein the metal of the first and second layers has at least one surface thereof having controlled heterogeneities thereupon.

Claim 31. The endoluminal stent according to claim 30, wherein the controlled heterogeneities are selected from the group consisting of grain size, grain phase, grain material composition and surface topography.

Claim 32. The endoluminal stent according to Claim 30, wherein the controlled heterogeneities define polar and non-polar binding sites for binding blood plasma proteins.

Claim 33. The endoluminal stent according to Claim 30, wherein the controlled heterogeneities are dimensioned to have a blood contact surface area substantially similar in size as endothelial cell surface integrin clusters.

Claim 34. The endoluminal stent according to Claim 30, wherein the controlled heterogeneities define cell-adhesion domains having interdomain boundaries less than the surface area of a human endothelial cell.

Claim 35. The endoluminal stent according to Claim 30, wherein the controlled heterogeneities form binding domains having a repeating pattern with no more than about 2 μm border to border spacing between adjacent binding domains.

Claim 36. The endoluminal stent according to Claim 30, wherein the controlled heterogeneities are dimensioned to have a blood contact surface area of about less than 6 μm^2.

Claim 37. The endoluminal stent according to Claim 30, wherein the controlled heterogeneity has a blood contact surface less than or equal to about 10 μm and an inter-heterogeneity boundary between about 0 and 2 μm.

9. Evidence Appendix

Previously Provided